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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/501,179	02/10/2000	Zheng-Pin Wang	1887.0060002/RWE/KKV	3508

7590

06/04/2002

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EXAMINER

CANELLA, KAREN A

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 06/04/2002

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/501,179

Applicant(s)
Wang et al

Examiner
Karen Canella

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 months MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 and 23-28 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 and 23-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

1. The finality of the Office action of Paper No. 13, mailed January 31, 2002 is withdrawn in light of the entry of applicant's amendment filed January 11, 2001.
2. Claim 22 has been canceled. Claims 1, 3, 6, 9, 19, and 21 have been amended. Claims 27 and 28 have been added. Claims 1-21 and 23-28 are pending and under consideration.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.
4. Claim 20 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 20 recites, "wherein metastatic cancer is present if the isolated cancer cells are proliferative cells". However, this is an embodiment already recited in part (d) of claim 19.

New Grounds of Rejection

5. Claims 1-19, 21, 23-28 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites "wherein the cancer cell classification comprises terminal cells and proliferative cells". It is unclear how a classifying a cell according to a type can comprise the cell type itself. For purpose of examination the claim will be read as "wherein the cancer cell is classified as terminal or proliferative".

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The recitation of “at least three cancer cells form a microtumor” in claim 11 has no antecedent basis in claim 1, as claim 1 is directed to the classification of cancer cells, not the enumeration of cancer cells.

The recitation of “intermediate cell” in claim 12 lacks antecedent basis in claim 1, as claim 1 is directed to the classification of cancer cells as terminal or proliferative, not intermediate.

Claim 14 recites, “natural body fluid sample”. It is unclear how a natural body fluid sample differs from an unnatural body fluid sample.

Claim 18 recites, “wherein cells are isolated using a circulating cancer cell test”. It is unclear how a test for the determination of the presence or absence of circulating cancer cells can contribute to the physical isolation of circulating cancer cells as recited in claim 1.

Claims 19 (c) and 21 (c) recite, “wherein the cancer cell classification comprises terminal cells and proliferative cells”. It is unclear how a classifying a cell according to a type can comprise the cell type itself. For purpose of examination the claims will be read as “wherein the cancer cell is classified as terminal or proliferative. Further, it is not clear how steps (b) differ from steps (c), as step (b) recites, “characterizing said isolated cells...to distinguish cancer cell classes” and step (c) recites “determining the classification of the cancer cells isolated”.

Claim 21 lacks an active method step relating the comparison of the cancer cell classifications determined in parts (c) and (f) with the assessment of the medical procedure in part (g).

The preamble of claim 21 recites, “A method of determining the efficacy of a medical procedure”. Part (g) recites, “assessing whether a medical procedure is efficient”. As efficiency is not the same as efficacy, it is unclear how the active method steps relate to the method objective as stated in the preamble.

6. The rejection of claims 1-21 and 23-26 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled

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in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is maintained for reasons of record (as stated in the Office action mailed May 1, 2001), and in addition, from the evidence as set forth in Wang et al (Cancer , 2000, Vol. 88, pp. 2787-2795, reference AS of the IDS provided on November 11, 2001). Claims 27 and 28 are rejected for the same reasons of record. Wang et al state on (page 2795, last paragraph):

“We are currently analyzing the profiles of these cell populations in view of the terminal pathway versus the living/multiplying pathway. Correlation of disease progression in these patients with the dynamic change of the circulating cancer cell population at different stages (in terms of total cell numbers and the distributions among classes/categories) may provide insight into the application of the circulating microtumor hypothesis described above to a clinical or diagnostic setting.” As this paper represents the work of the instant inventor which was submitted for publication on April 23, 1999 and the instant specification has a priority date of February 10, 1999, it is further evidence that at the time the application was filed, one of skill in the art would not be able to interpret the data obtained from the instant method of classifying cancer cells in terms of patient prognosis without undue experimentation. Further, this evidence corroborates the examiners rejection (page 3, lines 23-26) of the previous Office action which states that due to the lack of teachings in the specification regarding the link between the resulting classifications of isolated tumor cells in terms of absolute numbers and percentages and the positive diagnosis of metastatic cancer, one of skill in the art would not know how to use the instant claimed method.

7. Applicants amendment to claims 3 and 9 overcome the rejection under 35 U.S.C. 112, first paragraph, as stated on lines 16-25 on page 5 and lines 1-3 on page 6 of the Office action mailed May 1, 2001.


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8. All other rejections and objections as stated in Paper No. 13, mailed January 31, 2002 are withdrawn.

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Karen A. Canella, Ph.D.
Patent Examiner, Group 1642
June 3, 2002


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